APPENDIX F

QUALITY ASSURANCE AND QUALITY CONTROL GUIDANCE

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QUALITY ASSURANCE(QA) AND QUALITY CONTROL (QC) GUIDANCE

F.1 GENERAL QA AND QC CONSIDERATIONS

The primary objective of the specific QA and QC guidance provided in this document is to ensure that

- Appropriate data quality objectives or requirements are established **prior** to sample collection and analysis
- Samples are collected, processed, and analyzed according to scientifically valid, cost-effective, standardized procedures
- The integrity and security of samples and data are maintained at all times
- Recordkeeping and documentation procedures are adequate to ensure the traceability of all samples and data from initial sample collection through final reporting and archiving, and to ensure the verifiability and defensibility of reported results
- Data quality is assessed, documented, and reported properly
- Reported results are complete, accurate, and comparable with those from other similar monitoring programs.

F.2 QA PLAN REQUIREMENTS

To ensure the quality, defensibility, and comparability of the data used to determine exposure assessments and fish consumption advisories, it is essential that an effective QA program be developed as part of the overall design for each monitoring program. The QA program should be documented in a written QA plan or in a combined Work/QA Project Plan and should be implemented strictly throughout all phases of the monitoring program. The QA plan should include the following information either in full or by reference to appropriate standard operating procedures (SOPs):

1. A clear statement of program objectives

2. A description of the program organization and personnel roles and responsibilities, including responsibility for ensuring adherence to the QA plan

3. Specification of data quality objectives in terms of accuracy, precision, representativeness, and completeness, for data generated from each type of measurement system

4. Detailed descriptions of field sample collection and handling procedures, including documentation of

    - Target species and size (age) class
    - Sampling site locations
    - Target contaminants
    - Sampling times/schedules
    - Numbers of samples and sample replication strategy
    - Sample collection procedures
    - Sample processing procedures, including sample identification, labeling, preservation, and storage conditions
    - Sample shipping procedures

5. A detailed description of chain-of-custody procedures, including specification of standard chain-of-custody forms and clear assignment of field and laboratory personnel responsibilities for sample custody

6. Detailed descriptions of laboratory procedures for sample receipt, storage, and preparation, including specification of the kinds of samples to be prepared for analyses (e.g., composite vs. individual, whole body vs. fillet, replicates)

7. Detailed descriptions of the analytical methods used for quantitation of target contaminants, and percent lipid determination including

    - Specification and definition of method detection limits
    - Method validation procedures for verification of specifications for method accuracy, precision, and detection limits prior to analysis of field samples

8. Detailed descriptions of methods routinely used to assess data accuracy, precision, and completeness, including

- Internal QC checks using field, reagent, or method blanks; spiked samples; split samples; QC samples prepared from standard reference materials; and replicate analyses
- Calibration checks
- Data quality assessments

9. Detailed descriptions of calibration procedures for all measurement instruments, including specification of reference materials used for calibration standards and calibration schedules

10. Detailed descriptions of preventive maintenance procedures for sampling and analysis equipment

11. Detailed description of health and safety procedures

12. Detailed descriptions of recordkeeping and documentation procedures, including requirements for

    - Maintaining field and laboratory logs and notebooks
    - Use of standard data collection and reporting forms
    - Making changes to original records
    - Number of significant figures to be recorded for each type of data
    - Units of reporting
    - Routine procedures to assess the accuracy and completeness of records

13. Detailed descriptions of data analysis procedures, including

    - Statistical treatment of data
    - Data summary formats (e.g., plots, tables)

14. Detailed descriptions of data management and reporting procedures, including requirements for

    - Technical reports
    - QA and QC reports
    - Data coding procedures
    - Database specifications
    - QA review of reported data
    - Data storage and archiving procedures

15. Detailed descriptions of procedures for internal QC performance and/or systems audits for sampling and analysis programs.

16. Detailed descriptions of procedures for external QA performance and/or systems audits for sampling and analysis programs, including participation in certified QA proficiency testing or interlaboratory comparison programs.

17. Detailed descriptions of corrective action procedures in both sampling and analysis programs, including

    - Criteria and responsibility for determining the need for corrective action
    - Procedures for ensuring that effective corrective action has been taken
    - Procedures for documenting and reporting corrective actions

18. A description of procedures for documenting deviations from standard procedures, including deviations from QA or QC requirements

19. A description of the procedure for obtaining approval for substantive changes in the monitoring program.

Guidance for addressing each of the QA or QC elements outlined above, including a list of recommended standard reference materials and external QA or interlaboratory comparison programs for the analyses of target analytes, is incorporated in the appropriate sections of this guidance document.